**Pittsburgh Lifespan Sleep Databank (PLSD) Collaborative**

**Memorandum of Understanding**

**Investigator Overview**

Thank you for contributing your de-identified research data to the Pittsburgh Lifespan Sleep Databank (PLSD). The initial PLSD was developed by Drs. Meredith Wallace, Adriane Soehner, and Martica Hall through one year of pilot funding from the Clinical and Translational Science Institute (CTSI) at the University of Pittsburgh. This databank consists of harmonized participant-level data from existing sleep-related studies conducted at the University of Pittsburgh. Specific variables include daily actigraphy, retrospective self-reported sleep, and harmonized measures of mental/physical health and sleep disorder indicators. The overarching scientific aims of the pilot award were to use the harmonized PLSD data to: (1) characterize objective and self-report sleep health characteristics in *healthy adults* across the lifespan; and (2) examine differences by age, sex, and race.

Now that our pilot funding has ended, we plan to grow the initial PLSD in both scope (e.g., number of harmonized variables) and number (e.g., additional studies/protocols) through subsequent funding. The long-term goal is to make the PLSD a rich resource that investigators (internal or external) can use to tackle unanswered questions about aging, sleep, and health for years to come. To facilitate this, we are initiating a “PLSD Collaborative”, which you have already joined by contributing your de-identified data to the initial PLSD.

Being a member of the collaborative provides several benefits, including exclusive access to the PLSD for secondary data analysis and opportunities for co-authorship on PLSD-related research.

**The Collaborative’s scientific initiatives and policies will be guided and overseen by the “PLSD Working Group”, currently consisting of Meredith Wallace, Adriane Soehner, and Martica Hall.** The working group will carry the responsibilities of coordinating the overall project and conducting the initial pilot investigations. The working group will provide governance and oversight in the following areas:

(1) Organization

(2) Protection of authorship rights for members of the collaborative

(3) Direction for future analyses

(4) Ensuring work is performed in a timely manner

(5) Ensuring adherence to appropriate ethical guidelines

This document contains further details on:

* PLSD Phases
* Benefits and Responsibilities of members of the PLSD Collaborative and Working Group
* Frequently asked questions (e.g., What kinds of studies are eligible? What variables are being requested? How will the data be stored? How can I request data?)

**Currently, by providing de-identified data to the PLSD you are already part of this collaborative.** If you prefer to opt out of involvement, or if you have any questions, please email plsd@upmc.edu.

Below, we provide additional detailed related to the PLSD pilot award and collaborative. This project is approved by University of Pittsburgh Human Rights Protection Office: STUDY19040196.

**PLSD Pilot Award**

**Funding:** CTSI Pilot Award (Principal Investigators: Meredith Wallace, PhD & Adriane Soehner, PhD)

**Description**:

Your data were merged into a much larger database so that meta-analyses could be conducted. Only members of the PLSD Working Group had access to the dataset(s) you contributed, as well as the final merged database. All data are stored securely with password protection. **The final database includes de-identified participant IDs and protocols, harmonized sleep measures, basic demographics (age, sex, race, visit dates), and basic physical and mental health information.**

Investigators who contribute data remain owners of their own data. The procedures created by the PLSD Working Group to establish the merged database, such as syntax and codes, will be retained by the PLSD Working Group.

Drs. Meredith Wallace, Adriane Soehner, and Martica Hall analyzed the PLSD data to achieve the proposed aims:

* **Aim 1: Develop normative benchmarks for multidimensional, multimodal sleep across the healthy human lifespan using (a) ACT, (b) Diary, and (c) Retrospective Self-Report.** Flexible modeling techniques will be used to examine lifespan changes in sleep and summarize normative age-based benchmarks for each sleep domain (duration [total sleep time], timing [midsleep], regularity [midsleep variability], satisfaction [self-report quality], and alertness [napping]).
* **Aim 2:** **Determine when (and in which domains) age-related change in sleep differs by sex.** In light of well-documented sex disparities in sleep, sex will be tested as a modifier of age-related change in multidimensional, multimodal sleep; normative age-based benchmarks stratified by sex will be created.

These aims are published in:

Wallace ML, Kissel N, Hall MH, Germain A, Matthews KA, Troxel WM, Franzen PL, Buysse DJ, Reynolds CF III, Monk T, Roecklein KA, Gunn HE, Hasler BP, Goldstein TR, McMakin DL, Szigethy E, Soehner AM. Age Trends in Actigraphy and Self-Report Sleep Across the Lifespan: Findings from the Pittsburgh Lifespan Sleep Databank. Psychosomatic Medicine, *In press* (as of January 2022)*.*

**PLSD Collaborative**

**Timeline:** December 2021 – onward

**Description**: Upon publication of the pilot award specific aims, PLSD data and a description of the merged database (e.g., variables, sample sizes for variables) will now be made available to investigators who contributed data (i.e., the Collaborative) and their research teams. Investigators who wish to lead their own publications using the PLSD can apply to the PLSD Working Group for access to components of the merged database and lead their own investigations provided that they comply with the **Data Access Policy**below. We plan to keep the PLSD for collaborative use only for up to five years. After that, the PLSD may be submitted to a repository for widespread use; you will be given the opportunity to opt out if you prefer.

**Guidelines for PLSD Collaborative Analyses, Presentations, and Publications**

**Data access:**

1. Submit a data request form to the PLSD Working Group to access PLSD data.
2. Data requests will be reviewed monthly.
3. Requests will be reviewed by the PLSD Working Group to confirm scientific rigor and minimize overlapping analyses.
4. Data requests should be based on participant characteristics or outcome variables rather than by a specific protocol. Requests that specify protocols will be denied due to the deidentified nature of the PLSD.
5. Data requests that receive PLSD Working Group approval will then be circulated to PLSD members to invite collaboration on a project. PLSD members will have 14 days from the time of the posting to opt-in to be a co-author, ask for clarification, voice concerns or objections and/or give feedback to the proposal. If we do not hear from an investigator within 14 days, the PLSD Working Group will assume that the investigator does not want to be a co-author and approves the use of the data.
6. After the request is approved, the project lead will email a copy of the IRB approval letter to the PLSD working group prior to receiving data.

**Project lead responsibilities and guidelines:**

1. Circulate scholarly products (i.e., abstracts, presentations, manuscripts) resulting from approved PLSD analysis to co-authors and PLSD Working Group in advance of any deadlines (at least 2 weeks for abstracts and presentations; at least 1 month for manuscripts).
2. Conduct approved PLSD project in a timely manner. If projects have not demonstrated progress toward the approved aims after a year, and there is a similar data request, we will discuss the case with relevant parties and consider merging the projects.
3. The project lead will be responsible for assigning co-authorship order based on contribution to the conception, design, analysis and/or interpretation of the data; and drafting the manuscript or revising it critically for important intellectual content.

**Co-author responsibilities and guidelines:**

1. Approved data access requests will be circulated to PLSD members to invite collaboration on a project. PLSD members will have 14 days from the time of the posting to opt-in as co-author on the analysis.
2. Provide timely (within 1 month) review of manuscripts (i.e., confirm approval and/or provide feedback).
3. Provide information requested by the first or corresponding author necessary for submission within 1 month of a written request, including but not limited to contact information, address, conflicts of interest, grant numbers, etc.
4. Failure to comply with these guidelines will result in removal from a manuscript or other scholarly products.

**General authorship guidelines:**

1. Investigators who contribute de-identified data that contributed to the manuscript will be acknowledged in all publications. The PLSD Working Group will provide this information to a project lead.
2. Authorship for all PLSD Collaborative papers will be weighted by current effort and contribution. Collaborative members will be reasonable and self-critical in their claims for co-authorship. Contributing data to an analysis is sufficient to merit co-authorship, however the project lead will ultimately be responsible for assigning co-authorship order based on contribution to the conception, design, analysis and/or interpretation of the data; and drafting the manuscript or revising it critically for important intellectual content.
3. One of the members of the working group will be senior author on all PLSD publications, with exceptions granted on a case-by-case basis.
4. If a collaborative member does not contribute data to a given analysis, the expectation is that they will contribute to the conception, design, analysis and/or interpretation of the data; and drafting the manuscript or revising it critically for important intellectual content.
5. We request that the ‘PLSD Collaborative’ be included on the byline to reference the investigators of each study, in addition to contributors. In this way the authors contributing data to the PLSD will be appropriately acknowledged on any publication.

**Frequently Asked Questions**

**What kind of studies contributed data to the PLSD?**

Studies were eligible if they used actigraphy-based sleep monitoring.

**What kind of variables are included in the PLSD?**

The PLSD includes age (or year of birth plus year of enrollment/randomization), sex/gender, self-report and actigraphy measurements of sleep, depressive symptoms, sleep disorders, selected other physical and mental health conditions, and actigraphy measurement information. All data provided is de-identified both at the individual level and study level.  Please consult the data dictionary for more information: <https://www.sleep.pitt.edu/plsd/>

**Will my study be identifiable?**

In the PLSD, each study will be coded by a numeric ID; the key that links the IDs to your study will be password protected, and only accessible to the Working Group and honest broker data managers. Given the large number of studies involved in the final database, it is difficult but not impossible to re-identify specific studies. We will store the database with password protection. However, for publications the funding source will be acknowledged.

**Will re-analysis be carried out specifically for my study(s)?**

No. Publications arising from this project will utilize merged data from many studies. Studies will not be examined individually, but rather, collectively.  Further, access to the PLSD will be granted only when the investigators plan to carry out analyses on multiple (and not single) studies (see details in **Data Access Policy**).

**Do I need Internal Review Board (IRB) or Human Research Ethics Committee’s approval?**

Yes, investigators must contact their IRB to discuss to use of PLSD. An expedited and/or exempt process is expected to suffice because (1) only de-identified (no Protected Health Information, including no dates) data will be shared, and that (2) consent from participants would not be required as the purpose of the re-analysis is consistent with the research question of the initial study which they had already given consent.

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**PLSD Data Access Request Form Page 1**
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Date:

Investigator’s Name:

Department:

Telephone: e-mail:

Other investigators who will be working on this analysis:

Analysis Plan Title:

Purpose of Data Request (check all that apply):

Conference Abstract [ ] YES [ ] NO

 Pilot Data [ ] YES [ ] NO

 Manuscript [ ] YES [ ] NO

 Meta-Analysis [ ] YES [ ] NO

 Invited Talk [ ] YES [ ] NO

Who will perform the analyses?

Who will have access to the data?

Where will the data be stored?

Actigraphy data format requested: [ ]  Daily [ ]  Summary (e.g., average)

Please attach a 1-2 page description of your analysis plan. Please include the following:

1. Short background/rationale for addressing the research question
2. Eligibility criteria

3) Description of statistical methods

E-mail this completed form (as an attachment) to plsd@upmc.edu

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**PLSD Data Access Request Form Page 2**
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**PLSD data access is contingent upon signing the following statement:**

**I AGREE:**

1. To abide by the guidelines for authorship and publication, and other guidelines described in this document.

2. Not to distribute or copy any PLSD data without Working Group permission.

3. That the PLSD Working Group will review and evaluate data access requests to ensure scientific rigor and to limit duplicate analysis efforts.

4. Failure to abide to these guidelines may result in termination of the data access request.

**Signature Date**

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Please print name

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